Appendix 1: 510(k) Summary per 21CFR §807.92

Submitter's information

Stereotaxis, Inc.
4320 Forest Park Ave, Suite 100
St. Louis, MO 63108
Contact: Dennis Pozzo, Regulatory Affairs Specialist
Phone: 314-678-6136
March 30, 2007

AUG 24 2007

Device/ classification name

- Device Name:
  - Cardiodrive® CAS
- Classification/Common name:
  - Percutaneous Catheter & Wire, Guide, Catheter
- The marketed device(s) to which substantial equivalence is claimed:
  - Cardiodrive® Catheter Advancement System
  - Stereotaxis Cardiodrive® Catheter Advancer System
  - Stereotaxis Catheter Advancement System (CAS)

Device description

The Cardiodrive® provides a User Interface to control the motorized navigation of the catheter, in conjunction with the MNS magnetic fields. It is a tool that provides the physician with the ability to advance and retract magnetic EP catheters. The Cardiodrive® is designed only for use with compatible magnetic EP mapping catheters inside the patient's heart steered with a Stereotaxis MNS.

Intended use

The Stereotaxis Cardiodrive® is intended for automatically advancing and retracting only compatible magnetic electrophysiology [EP] mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis Magnetic Navigation System (MNS). It is not intended to advance the EP mapping and ablation catheters through the coronary vasculature nor the coronary sinus.

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Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Technological characteristics

There have been no modifications to the Cardiodrive CAS. The table below lists device characteristics.

Device Characteristic	Proposed Cardiodrive® CAS	Predicate Cardiodrive® CAS
Catheter Retraction/Advancement	Mechanical	Mechanical
Variable Speed	Yes	Yes
Catheter Movement	Stepped or Continuous	Stepped or Continuous
Emergency Stop Option	Mechanical or Manual	Mechanical or Manual
Manual Override	Yes	Yes
Stop Switch	Yes	Yes

Performance data

Based upon the objective evidence presented in this 510(k) it has been demonstrated that any compatible magnetically tipped EP ablation catheter can be used safely and effectively when used with the Cardiodrive® CAS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2007

Stereotaxis, Inc.
c/o Mr. Dennis Pozzo
Regulatory Affairs Specialist
4320 Forest Park Ave.
Suite 100
St. Louis, MO 63108

Re: K071029
Trade/Device Name: Cardiodrive Catheter Advancement System (CAS)
Regulation Number: 21 CFR 870.1330
Regulation Name: Wire, Guide, Catheter
Regulatory Class: Class II
Product Code: DQX
Dated: July 26, 2007
Received: July 27, 2007

Dear Mr. Pozzo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of

the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 2: Indications for Use Statement

Statement

The indications for Use Statement:

510(k) Number: K 071029

Device Name: Cardiodrive® Catheter Advancement System (CAS)

The Stereotaxis Cardiodrive is intended for automatically advancing and retracting only compatible magnetic electrophysiology [EP] mapping and ablation catheters inside the patient's heart when used in conjunction with a Stereotaxis Magnetic Navigation System (MNS). It is not intended to advance the EP mapping and ablation catheters through the coronary vasculature nor the coronary sinus.

Prescription Use ___X___ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Volkmer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071029